

# FACT

## FOOD ANIMAL CONCERNS TRUST

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RE: Docket No. 97N-0074

February 11, 2000

To whom it may concern:

Enclosed please find The Comments of Food Animal Concerns Trust in response to the Draft Preliminary Food Safety Strategic Plan for Public Review.

Thank you for providing this opportunity for contributing stakeholder input during the process of determining the substance and structure for the new United States food safety system.

Sincerely,



Richard R. Wood  
Executive Director



Meryl Camin Sosa  
Manager, Food Safety Programs

97N-0074

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## FOOD ANIMAL CONCERNS TRUST

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The Comments of Food Animal Concerns Trust  
in response to the Draft Preliminary Food Safety Strategic Plan for Public Review

February 11, 2000

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

DOCKET NO. 98-045N

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Food and Drug Administration

DOCKET NO. 97N-0074

Food Animal Concerns Trust (FACT) is a non-profit organization that advocates for the use of better farming practices to improve the safety of meat, milk, and eggs. The President's Joint Council on Food Safety (the Council) has been presented with a valuable opportunity to make substantial changes to the current food safety system so that the food consumed in the United States truly is the "safest in the world." To that end, FACT wants a system that is led by one agency, with one purpose, having clear roles and responsibilities, that can enforce what it regulates, and that starts where food starts--on the farm. We want this system to be focused entirely on food safety, where the American public will know who is responsible.

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## I. ORGANIZATIONAL CONSIDERATIONS

Prior to any consideration of the goals and specific action items set forth in the Draft Preliminary Food Safety Strategic Plan for Public Review (the Plan), the Council must first address the critical issue of the organizational structure for the United States food safety system. The current food safety system has at least 12 agencies involved in the key functions of food safety. Over 50 memoranda of agreement exist between the various agencies related to food safety.<sup>1</sup> Finally, more than 35 federal statutes regulate food safety.<sup>2</sup> These figures do not even take into account the numerous state and local food safety related regulations. Clearly, the current federal food safety system is "complex, fragmented and cumbersome."<sup>3</sup> This state of affairs is untenable and must be changed.

FACT agrees with the recommendation by the Committee, of the National Research Council, to Ensure Safe Food from Production to Consumer (the Committee), that an independent single agency at the cabinet level would be the most effective method for ensuring the safety of food in the United States. A person, who would be a member of the President's cabinet, should have both legal authority and budgetary control for food safety. Legal authority is necessary so that important decisions can be made quickly, efficiently, and effectively without the perpetual need for obtaining a consensus, among the coordinating agencies, on key issues. Budgetary control is fundamental in order that food safety is adequately funded and so that funds intended for food safety programs are not siphoned off to other programs. A single food safety budget will also make it clear to

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<sup>1</sup> Id.

<sup>2</sup> Id. at 7.

<sup>3</sup> Committee to Ensure Safe Food from Production to Consumer, Institute of Medicine, National Research Council, Ensuring Safe Food From Production to Consumption, National Academy Press, 1998 at 23

the public that the federal government is placing sufficient emphasis on the issue of food safety. By having budgetary control, long term strategies can be more effectively implemented than under the current circumstances where long term strategies cannot be established because food safety funding is evanescent. The current short-term focused system emphasizes a crisis based approach since it is not known whether the food safety system will be funded from year to year. Therefore, long-term strategies are essential because they will permit a more thoughtful science-based approach to the problem of food safety.

**A single food safety agency would eliminate the conflict of interest issue posed by the current food safety system.**

In the current food safety system, the regulatory agencies, responsible for food safety, often have dual purposes that may stand in opposition to each other, diminishing agency effectiveness in addressing food safety as well as diminishing consumer confidence in the United States food safety system. Several examples will illustrate this issue.

First, the United States Department of Agriculture (USDA) addresses food safety under the double mandate to both regulate portions of the food industry and promote its products. The juxtaposition of these two purposes within one agency conceivably places the interests of the food industry over and against the food safety needs of consumers.

Second, a conflict of interest is evidenced by a recent decision made by the United States Food and Drug Administration (FDA) in a document entitled "FDA Response to Comments on A Proposed Framework for Evaluating and Assuring the Human Food Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in

Food-Producing Animals” (FDA Response).<sup>4</sup> In the FDA Response, FDA states that the National Antimicrobial Resistance Monitoring System (NARMS) would be inadequate to assess the safety of specific food animal antimicrobials, stating,

The monitoring program is only a sentinel system and has a number of inherent limitations. Although it is possible to identify that a problem exists, the magnitude of the problem is difficult to assess with the monitoring system data alone. NARMS is not capable of identifying how or why the resistance occurred. Data related to the resistance findings, such as demographic information and history of drug use, is not collected in the animal populations and NARMS can not be modified to obtain that information. . . Due to these limitations, the data can not be linked to particular practices of concern. Moreover, it is important to point out that further expansion or enhancement of NARMS will not solve the problem or minimize the limitations.<sup>5</sup>

Despite FDA’s analysis above, FDA concludes, in the FDA Response,

due to the number of comments objecting to the studies, FDA has decided not to propose that on-farm monitoring be a post-approval requirement and instead rely on the NARMS program to track loss of susceptibility or development of resistance.<sup>6</sup>

Other than this conclusion, no analysis supporting FDA’s decision was included in the FDA Response. Since pharmaceutical companies would be the parties responsible for performing post-approval studies, it can be inferred that it was the comments of the pharmaceutical companies which persuaded FDA to concede on this issue. Therefore, in this transparent example of a conflict of interest, it is obvious that the interests of the animal pharmaceutical companies were given priority over those of the American public.

**The new single food safety agency should be empowered with regulatory authority as well as enforcement powers.**

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<sup>4</sup> FDA Response to Comments on A Proposed Framework for evaluating and Assuring the Human Food Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals, Food and Drug Administration (FDA) Center for Veterinary Medicine (CVM), December 1999.

<sup>5</sup> Id. at 43.

The current food safety system does not confer sufficient enforcement powers upon the agencies entrusted with the authority to regulate food safety. Several examples will illustrate this point. First, the FDA can conduct traceback investigations where a foodborne illness outbreak has occurred, but the FDA does not have the authority to force the company to recall the products that caused the outbreak.

Second, the FDA has the authority to approve new animal drugs, but it does not have the authority to press charges when there has been a food animal drug violation. Third, FDA has the authority to approve drugs for subtherapeutic uses, but it does not have the authority to withdraw such drugs from the market where antibiotic resistance has developed unless it can prove there is "an imminent hazard to the health of man or animals."<sup>7</sup>

Fourth, the USDA can adopt regulations that require companies to comply with HACCP, but the USDA cannot force a company to recall contaminated or adulterated products, even if they occur as a result of HACCP violations.<sup>8</sup> An agency decision to withdraw inspections may stop the plant from marketing more products, but it does nothing to address the public health risks arising from the product in question. However, recently, USDA's authority even to withdraw inspections has been questioned by the industry in the Supreme Beef Processors (SBP) case in Texas. In that case, after SBP had failed three consecutive sets of salmonella performance standards tests, which are required by HACCP, USDA withdrew its inspectors from

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<sup>6</sup> Id. at 44.

<sup>7</sup> 21 USCS Section 360b; Sundlof says CVM lacks legal authority for blanket antibiotic ban, Food Chemical News, March 22, 1999, at 4.

<sup>8</sup> Poisoned Package, The Washington Post, January 16, 2000, at 12.

the plant, effectively closing the plant. In response, SBP obtained a restraining order requiring the USDA to reinstate its inspectors at the plant. In granting the restraining order, the judge suggested that the USDA may have exceeded its authority in establishing tougher salmonella inspection standards.

The example provided by the SBP case clearly illustrates the problems facing the various food safety agencies acting under the current set of statutes and regulations because their authority may not be explicitly provided by statute and, therefore, may be open to question. The authority of the federal agencies entrusted with the responsibility for protecting the American public health should not be open to question. If a single food safety agency were created and the new agency overhauled the relevant statutes and regulations, then authority would be clearly established and the agency would have the necessary authority to ensure the safety of food.

**Coordination between the existing federal agencies is not an adequate alternative to a new single cabinet level food safety agency.**

The establishment of a council comprised of heads of existing agencies will do nothing more than create minor changes in the current system. In order for any new food safety system to constitute a significant improvement, the entire current system must be completely reconstructed. Rather than merely modifying the current system, a new food safety system must be created including a completely new statutory and regulatory structure. While this task may appear daunting and expensive, in the long-term, the benefits realized from the new system will outweigh the costs.

The need for a system comprised of persons that do not have vested interests in the current system is illustrated by the following example. The Committee made a

recommendation, in its report, that the continuous inspection system for meat and poultry be eliminated and replaced with a science-based approach which is capable of detecting hazards of concern.<sup>9</sup> Congress' decision to statutorily require physical carcass-by-carcass inspection was appropriate for those hazards present 70 years ago as most hazards were visible. However, the hazards of greatest concern today are microbiological and chemical contamination which are not detectable by traditional inspection methods: look, sound, smell and feel. Not only has this recommendation been made by the Committee, but the United States General Accounting Office (the GAO) made this recommendation as well after a thorough analysis of the issue. Currently, the budget for the continuous inspection is approximately \$271 million, which represents one-fourth of the federal government's food safety spending.<sup>10</sup>

In spite of the fact that the continuous inspection law is clearly outdated in terms of its application to modern problems, the "law's demand has for decades influenced funding of meat and poultry regulation."<sup>11</sup> Its influence continues to be expressed by USDA leadership.<sup>12</sup> As a result, the Plan fails to include any action items wherein the issue of the continuous inspection system is evaluated. How can consumers rely on the Council members to make a decision that will protect the public health of Americans when the Council members have so much to lose?

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<sup>9</sup> Committee to Ensure Safe Food from Production to Consumer, Institute of Medicine, National Research Council, Ensuring Safe Food from Production to Consumption, National Academy Press, 1998, at p. 94.

<sup>10</sup> FSnet September 9, 1998.

<sup>11</sup> Id.

<sup>12</sup> Secretary of Agriculture Dan Glickman said that it would be a "terrible mistake to give up on continuous inspection right now" and that such a dramatic change in inspection would need "serious scientific consideration." (Food Chemical News, August 31, 1998 at 3, 28) Undersecretary of Food Safety Catherine Woteki has also defended the system saying that the system has benefited public health for many decades and would continue to do so in the future. (Food Chemical News, September 28, 1998, at 17) This sentiment has been echoed by FSIS Administrator Tom Billy. (Id.)



**The experiences of four countries in consolidating their food safety systems support a change in the United States to a single food safety agency.**

In May, 1999, the GAO published a report in which it analyzed the experiences of four countries in consolidating their food safety systems. The experiences of these four countries should be used by decisionmakers in the process of deciding which option in the Plan would be the best for protecting the consumer health. While all four countries are incurring short term start-up costs in establishing their new agencies, they all expect to experience long term benefits in terms of money saved, more food safety for the money spent and/or better assurance of food safety. In addition, officials from these four countries expect the following benefits: improved service delivery by providing a single contact for consumer and industry clients; reduced overlap and duplication of services; improved or reduced need to coordinate food safety activities, thereby enhancing the efficiency and effectiveness of food safety regulations; and provision of more comprehensive oversight of food safety from farm to table.

In August, 1999, the GAO, in testimony before the Subcommittee of Government Management, Restructuring and the District of Columbia, Committee on Governmental Affairs, of the United States Senate, stated that "a single food safety inspection agency responsible for administering a uniform set of laws is the most effective way for the federal government to resolve these long standing problems, deal with emerging food safety issues, and better ensure a safe food supply."<sup>13</sup> The GAO based their conclusion on six primary reasons:

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<sup>13</sup> United States General Accounting Office, Testimony Before the Subcommittee on Oversight of Government Management, Restructuring and the District of Columbia, Committee on Governmental

1. "Federal agencies are not using their inspection resources efficiently."
2. "Responsibilities for the oversight of chemical residues in foods are fragmented among FDA, USDA and EPA."
3. "Enforcement authorities granted to the agencies also differ."
4. "Oversight of imported food is inconsistent and unreliable."
5. "Fragmented federal responsibilities also cause problems for the food industry."
6. "The agencies have made attempts to coordinate their activities to overcome the fragmentation and avoid duplication or gaps in coverage, but history has shown that as time passes, such efforts frequently prove to be ineffective."<sup>14</sup>

The GAO, and many members of the Committee who support a single food safety agency, has supported its conclusion with a cogent analysis based on facts relating to the fragmented United States food safety system as well as an analysis of those countries adopting a new food safety system in response to either perceived government mishandling of foodborne illness crises or concerns about program effectiveness and cost savings. On the other hand, the Council has chosen to simply list the different organizational options without any analysis whatsoever. Further, after the stakeholder meeting in July, 1999, Secretary of Agriculture Dan Glickman told the media that the Council opposes the creation of a single food safety agency providing, as the only reasons ever stated against the creation of such an agency, that the creation would be disruptive and might cause more food safety problems.<sup>15</sup> Other than these reasons, no analysis has

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Affairs, U.S. Senate, Food Safety: U.S. Needs a Single Agency to Administer a Unified, Risk-Based Inspection System, August 4, 1999, (the GAO Food Safety Report) at p.1.

<sup>14</sup> Id. at 4-5.

<sup>15</sup> Food Safety Council opposes single food agency, Food Chemical News, July 19, 1999 at 22-24.

ever been provided by any federal agency stating why the creation of a single food safety agency would not be in the best interests of the American public.

As stated by the GAO, in order to protect the public health, we need a food safety system that includes

A clear commitment by the federal government to consumer protection, a system that is founded on uniform laws that are risk-based, adequate resources devoted to that purpose, and competent and aggressive administration of the laws by the responsible agency.

**General/Cross-cutting Question Regarding the Draft Plan:**

- 1. Is the overarching goal and overall framework of the plan well-focused and comprehensive? What modifications would you suggest? What issue or concern would your modification address?**

FACT believes the Plan should include, overall, a greater emphasis on farm based controls and mitigation strategies that can be used to improve food safety. Pre-harvest controls are necessary for several reasons. First, livestock and poultry are reservoirs for the principal foodborne disease agents.<sup>16</sup> Second, while these bacteria do occasionally produce disease signs in infected livestock, disease signs are rare compared to the frequency of gastrointestinal tract colonization.<sup>17</sup> Third, researchers have indicated that the presence of foodborne disease may increase as farms become larger and more contained.<sup>18</sup> The study documented how the pathogen load in swine herds increased as the size of the herd increased: from the 32.2 percent for herds less than 2,000; to 45.6 percent for herds marketing 2,000 to 9,999; to 57.1 percent for herds in excess of

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<sup>16</sup> Dale Hancock and David Dargatz, Implementation of HACCP, HACCP Symposium, November 1995, at 1.

<sup>17</sup> Id.; USDA/APHIS, Shedding of Salmonella by Finisher Hogs in the United States, January 1997 at 1.

<sup>18</sup> Hueston, William D., Paula J. Fedorka-Cray, Pathogen Identification on the Farm and the Impact of Farm Management Strategies, Tracking Foodborne Pathogens from Farm to table, An Economic research Service Report, Conference Proceedings, January 9-10, 19995, at 65.

10,000.<sup>19</sup> Since the trend over the past 18 years has been an increase in the concentration of animals in food production<sup>20</sup>, management strategies must be mandated that address the hazardous by products of this change in animal production. Some examples of on-farm animal husbandry methods that could be used to decrease the incidence of pathogens on-farm include: pelletization of poultry feed<sup>21</sup>; keeping cattle water troughs clean and regularly changing the water<sup>22</sup>; shock chlorination (short term addition of chlorine to water at a much higher level than present in municipal drinking water)<sup>23</sup>; decreased stress on feedlots<sup>24</sup>; reduce overcrowding of animals<sup>25</sup>, increased biosecurity measures including protection of feed from contamination by birds and other mechanisms, changing the type of feed<sup>26</sup>; and use of propionic and acetic acids to inhibit

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<sup>19</sup> USDA/APHIS, Shedding of Salmonella by Finisher Hogs in the United States, January 19997 at 2.

<sup>20</sup> Between 1982 and 1997, the number of hog farms dropped from 600,000 to 157,000, yet these farms still produce about the same number of hogs. Animal Waste Pollution in America: An Emerging National Problem, Environmental Risks of Livestock & Poultry Production, Report Compiled by the Minority Staff of the United States Senate Committee on Agriculture, Nutrition, & Forestry for Senator Tom Harkin, December 1997 (the "Senate Report") at 3.

<sup>21</sup> McCapes, RH, HE Ekperigin, WJ Cameron, WL Ritchie, J. Slagter, V. Stangeland, and KV Nagaraja, Effect of a New Pelleting Process on the Level of Contamination of Poultry Mash by Escherichia coli and Salmonella, Avian Diseases 33:103-111, 1989, at 103.

<sup>22</sup> Research has shown that water troughs are an important source of E. coli 0157:H7 and generic E. coli. The pathogen can survive for at least four months in water trough sediments. Epidemiologist questions role of feed in spreading contamination among herds, Food Chemical News, September 15, 1997, at 4. Research has shown that keeping water troughs clean and regularly changing the water for cattle appear to be the most effective barriers to the disease. Clean farms are health farms. AnimalNet May 15, 1998.

<sup>23</sup> Correspondence with Dr. Dale Hancock October 16, 1997.

<sup>24</sup> The 1994 National Animal Health Monitoring System's (NAHMS) Cattle on feed Evaluation (COFE) identified the length of time cattle are on a feedlot as a factor. Pens of cattle in a feedlot for a shorter time (less than 20 days) had an increased likelihood of shedding E. coli 0157:H7. Stresses and short periods when cattle are off feed during transportation are two possible contributing factors. Factors Associated with E. coli 0157:H7 in feces of Feedlot Cattle, Fsnets November 21, 1997. Evidence exists that stress influences intestinal flora. LP Garber, SJ Wells, DD Hancock, MP Doyle, J. Tuttle, JA Shere, T Zhao, Risk Factors for fecal shedding of E. coli 0157:H7 in dairy calves, Journal of American Veterinary Medical Association, Vol. 207:46-49 (1995).

<sup>25</sup> "Animals that are overcrowded and must compete for feed, water, and sleeping space are more susceptible to disease." The Use of Drugs in Food Animals: Benefits and Risks, National Research Council, Institute of Medicine, Washington, DC 1998, at 164.

<sup>26</sup> Research has shown a significantly higher prevalence of E. coli 0157:H7 in herds where corn silage was fed to heifers than in herds where the heifers' diet did not include corn silage. The basis for this association may be that once corn silage is removed from the silo, exposed to air and mixed with other ingredients, corn silage could provide a moist growth medium for environmental bacteria, including E. coli 0157:H7. E. coli can replicate to high concentrations in mixed rations containing corn silage when it is

growth of fecal *E. coli*.<sup>27</sup> Many on-farm controls are inexpensive, yet effective. Thus, if the incidence of pathogens can be reduced on-farm, the need, and concomitant costs, of technologies required by slaughterhouses and processing plants to eliminate or decrease pathogens can be lessened at that point.

Second, the Plan fails to include any action items related to the issue of animal waste. The statistics describing animal waste pollution in the United States are astounding.<sup>28</sup> Approximately 1.4 billion tons of animal manure are produced every year. Nationwide, 130 times more animal manure is produced than human waste.<sup>29</sup> In fact, five tons of animal waste is produced for every person in the United States. Obviously, this is a serious issue.

While we no longer allow people to dump their untreated human waste in their backyards, this is precisely what we permit CAFOs to do with animal waste. Moreover, by not uniformly regulating the issue, on a national basis, we also allow untreated animal waste to be used as fertilizer on the crops we eat (even on fruits and vegetables that are eaten raw) and to be used as feed for other livestock. Recent studies have found bacterial

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maintained at environmental temperatures for 24 hours. Cattle rations containing silage are commonly left in the feed bunk for a period of 24 hours or more, thereby permitting an opportunity for both contamination with bacteria and bacterial replication. DD Herriott, DD Hancock, E. Ebel, LV Carpenter, DH Rice, and TE Besser, Association of Herd Management Factors with Colonization of Dairy Cattle by Shiga Toxin-Positive *Escherichia coli* 0157, *Journal of Food Protection*, Vol. 61, No. 7, pp. 802-807 (1998); Also, a study found that pens receiving barley in the ration were 2.75 times more likely to have a positive sample than pens not receiving barley. Factors Associated w/*E. coli* 0157 in Feces of Feedlot Cattle The 1994 National Animal Health Monitoring System's (NAHMS) Cattle on feed Evaluation (COFE) October 1997.

<sup>27</sup> Food Chemical News, September 15, 1997, at 4.

<sup>28</sup> It is estimated that 1.37 billion tons of manure (which does not include other types of farm waste such as dead animals, used bedding, waste feed and other residual organic matter) are generated each year. Senate Report at 2. For example, each dairy cow produces 120 pounds of waste per day. Los Angeles Times article reprinted in AnimalNet 4/28/98. California is the largest dairy producing state. As such, the more than 1600 dairies in the Central Valley of California produce more waste than a city of 21 million people, yet there are no regulations requiring that this phenomenal amount of waste be properly managed and processed. Senate Report at 3. Swine operations also produce prodigious amounts of animal waste. A 50,000 hog swine production facility in southwest Utah, designed to produce 2.5 million hogs annually, has a potential waste output greater than the entire city of Los Angeles. Senate Report at 11.

isolates, such as Salmonella, E. coli and Enterococcus, in samples from manure lagoons and groundwater from nine swine CAFOs.<sup>30</sup> In addition, the study found Enterococcus faecium was resistant to 11 antimicrobials, including six antimicrobials used in human medicine.<sup>31</sup> Thus, since manure harbors pathogenic bacteria and/or antimicrobial resistant bacteria, such bacteria are passed along through the food chain either through water, feed or as foodborne pathogens. Animal waste from the large confinement animal feeding operations is a food safety issue.

The federal agencies currently charged with the responsibility for animal waste, the USDA and the EPA, have chosen to govern the issue by publishing the Guidance Manual and Example Permit for Concentrated Feeding Operations-Review Draft (the Manual).<sup>32</sup> The Manual is inadequate for a variety of reasons, including the following: the Manual leaves many issues to the discretion of the states; fails to address the issues of groundwater, odor, abandoned lagoons, poultry litter, and animal waste used as animal feed; and leaves 95 percent of all animal feeding operations subject only to voluntary cooperation with the program.

The fact that the Plan fails to address the issue of animal waste as a component of the United States food safety system indicates the Council's failure to recognize the importance of this issue and its relevance to food safety. The Plan states "the Administration has adopted a farm-to-table approach that looks at food safety as an

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<sup>29</sup> Senate Report at 1.

<sup>30</sup> Campagnolo, Enzo R., Chemical and Microbial assessment of surface and groundwater proximal to large-scale swine operations, Iowa, 1998 CDC-Health Studies Branch.

<sup>31</sup> The Enterococcus faecium were resistant to clarithromycin, tetracycline, erythromycin, lincomycin, gentamicin, and penicillin. Id.

<sup>32</sup> Guidance Manual and Example Permit for Concentrated Animal Feeding Operations-Review Draft, August 6, 1999.

integrated and interdependent system.”<sup>33</sup> Animal waste is a by-product of the animals in our food production system. Further, animal waste is used as feed for food production animals. Thus, how can the issue not be included in the Plan? Specific action items, regarding this issue, will be included as recommendations throughout the remainder of these Comments.

A final general consideration is the lack of any timelines in the Plan. FACT believes that some timelines should be included so that places where serious delays may occur may be analyzed so that it may be determined whether the specific proposal can be reevaluated and a more expeditious method developed.

**Science and Risk Assessment Goal: The United States’ food safety system is based on sound science and risk assessment.:**

**Objective 3: Develop and implement a unified, risk-based problem-solving research agenda particularly aimed at bridging identified gaps.**

**Action items:**

**Use risk analysis to identify gaps and establish priorities for a unified food safety research agenda.**

**This agenda should provide the basis for scientifically sound food safety policies and programs. The scope of the unified program should include: microbial hazards; chemical contaminants; regulated, pre-market approved ingredients and processes; pesticides; physical hazards; water used for food production and processing; animal feed; and veterinary drugs and biologics and drug and biologic residues.**

Several issues are raised by this action item. First, why is the focus of this action item limited to water used for food production and processing? Water intended for use by humans should be governed by an agency entrusted with the responsibility for safe food. This is particularly important since the issue is not adequately addressed elsewhere, especially water from farm wells used by farmers for drinking water. The Manual addresses only issues related to surface water and fails to address issues related to

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<sup>33</sup> Draft Preliminary Food Safety Strategic Plan for Public Review (the Plan), January 7, 2000 at p. 5.

groundwater which can impact the human water supply. Untreated animal waste sprayed onto farm fields and spillage from waste lagoons can also have a substantial impact on human drinking water.

The Plan also states that the unified program should include animal feed. However, this reference is vague. For example, will the program include regulation of animal waste, such as poultry litter, that is used as animal feed? Studies have shown that antibiotic resistance can be transferred through, at a minimum, poultry litter.<sup>34</sup> Therefore, this area should be regulated to protect consumer health.

Finally, the scope of the unified program should include, under veterinary drugs and biologics, research into issues related to the subtherapeutic use of antibiotics. In light of the increasing incidence of antibiotic resistant bacteria, research should be performed to learn more about the reasons antibiotics increase growth, the extent of residues remaining in animals at the time of slaughter, and alternatives to antibiotics to improve growth in food production animals. Recently, a study found that antibiotics do not actually spur growth. Instead, they preclude a side effect of poultry's immune system: invading pathogens trigger white blood cells to release chemicals, called cytokines, that suppress the appetite. Mark E. Cook, a University of Wisconsin animal scientist, has created a special molecule that mops up the cytokines. When his compound was added to

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<sup>34</sup> Mark Zervos, MD, Epidemiology of antimicrobial resistance in human and animal isolates of Enterococci, Food Safety Symposium on Antimicrobial Resistance, September 24, 1999, Centers for Disease Control and Prevention; Judy Johnson, PhD, Synercid resistant Enterococcus faecium in a commercial poultry farm, Food Safety Symposium on Antimicrobial Resistance, September 24, 1999, Centers for Disease Control and Prevention; Kirk Smith, DVM, PhD, Current trends in quinolone resistant Campylobacter jejuni infections in Minnesota, Food Safety Symposium on Antimicrobial Resistance, September 24, 1999, Centers for Disease Control and Prevention; Enzo Campagnolo, DVM, MPH, Investigation into the chemical and microbial constituents of surface and ground water proximal to large scale swine and poultry feeding operations, Food Safety Symposium on Antimicrobial Resistance, September 24, 1999, Centers for Disease Control and Prevention; Charles Hofacre, DV, MAM, PhD, Update on research in food safety from the Department of Avian Medicine at University of Georgia, Food



chicken feed, the chickens grew just as fast as those receiving antibiotic laced feed.<sup>35</sup> Given the dangers inherent in the subtherapeutic use of antibiotics, it is no longer appropriate to deny the problem. Instead, the Plan must include programs that address this issue.

**Objective 5: Enhance scientific infrastructure and skills at federal, state, and local levels.**

Policy making decisions, affecting food safety, should not be left to state and local governments. The United States is an interdependent set of states where pollution in one state may have a direct impact on another state. Thus, a system that allows states to make decisions independently allows states to take a benefit without accepting the concomitant cost of such decisions. If a single food safety agency were implemented, such inequities would be observed, and then regulated in a uniform manner.

The fact that a coordinated system will not work is demonstrated by the Manual's (a collaboration between EPA and USDA) continuation of the policy of allowing many decisions regarding animal waste and surface water to be decided by the states. This is unacceptable as it perpetuates a situation that the Manual was supposed to address—declining water quality as a result of agricultural runoff. The problem is depicted by the following example:

During the last five years, Virginia and Delaware have tolerated substantial spills from slaughterhouses operated by Allen Family Foods, Townsends and Perdue, without fining them or going to court to compel plant improvements. Maryland has been the dump site for millions of gallons of slaughterhouse waste that Perdue trucks in from its plants in Delaware, because Delaware limits disposal while Maryland doesn't.

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Safety Symposium on Antimicrobial Resistance, September 24, 1999, Centers for Disease Control and Prevention.

<sup>35</sup> Use chicken feed in the war on superbugs, Business Week Online, AnimalNet February 5, 2000.

Slaughterhouses are the chicken industry's most tightly regulated sector. Yet the rules allow plants to legally dump harmful amounts of waste. State regulators have not adequately confronted deteriorating water quality, according to an internal report by the U.S. Environmental Protection Agency's Water Protection Division. Instead, they set arbitrary and loose pollution controls, the EPA concluded after inspecting 21 chicken plants in the mid-Atlantic in 1997, including 14 in Maryland, Virginia and Delaware.<sup>36</sup>

As illustrated above, the decision to allow States to make decisions that impact water quality allows inequity in the type of protection consumer health will receive.<sup>37</sup>

**Action items:**

**Establish extramural programs (e.g. Centers of Excellence) to conduct targeted research and develop training programs linked to food safety and public health.**

**Through new and available mechanisms (e.g. public/private/academic consortia, cooperative research and development agreements), provide targeted research programs linked to priority needs of food safety public health professionals and train present and future generations of food safety scientists.**

FACT supports a cooperative and targeted approach to food safety research. However, FACT believes that consumer groups should be able to participate in the decision making process as to what studies are needed and what studies should be funded. Certain research is not performed because there is no incentive, on the part of industry, to perform such research. Yet the results of such research would certainly be relevant to their industry.

The following are examples of types of studies that FACT would want to be funded, which would not be performed by researchers funded by industry, but which may disclose other methods for mitigating foodborne illness:

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<sup>36</sup> Permitting a Pattern of Pollution, Poultry's price: The Cost to the Bay, The Washington Post, August 2, 1999 at A10.

<sup>37</sup> Another example of the disparity of environmental safeguards is provided by the rules of Maryland, Virginia and Delaware regarding individual wells. "Maryland requires tests for nitrates when a new well is drilled or when property changes hands. Virginia requires tests only for new wells. Delaware has no such requirements although mortgage companies usually require tests." An Unsavory Byproduct, Poultry's Price: The cost to the Bay, The Washington Post, August 1, 1999, at A21.

1. Research that compares the Salmonella enteritidis (SE) contamination rate between deep litter floor systems and cage systems;
2. Research into which breeds of layers are more susceptible to SE (so that strains that are less susceptible to SE are used)
3. Research that determines the relationship, if any, between hen density in cages and the shedding of SE;
4. Whether antibiotic resistant bacteria are in hog lagoons and, if so, what types and are they multi-resistant?
5. What bacteria and/or chemicals are in the odor emitted from hog lagoons and what impact are they having on neighbors to the lagoons?
6. Research into cost-effective methods for handling animal waste including methods for cost-sharing among small farms and the federal government;
7. Research into animal production without the subtherapeutic use of antibiotics.

**Risk Management Goal: The United States system for managing food safety is effective from farm to table.**

**Objective 1: Identify where risk management gaps exist in the current food safety system.**

**Action items:**

**Using risk criteria determine where standards are needed or need to be harmonized between state and federal and among federal programs and develop a plan to meet these needs.**

**Identify national, state, and local standards and regulations that are in place to address these areas and assess their potential to be the basis for national standards.**

**Build the infrastructure required to support a seamless, federal/state/local food safety system.**

**Near-term work includes a gap analysis and identification of criteria to improve effectiveness of programs at all levels.**

First, we have the following questions regarding the “risk criteria” referenced in the first action item:

1. What are “risk criteria?”
2. Who determines what the “risk criteria” should be when standards are needed?
3. What is the process for determining what “risk criteria” will be used in each situation?
4. Will the process be transparent, that is, will stakeholders, including consumer groups, have an opportunity for involvement in the process?

Second, while knowledge of existing state and federal programs may be useful in providing background for an issue, it must be remembered that the reason that the Plan was even initiated is the current food safety system is not effective and, moreover, is not perceived, by the American public, to be effective.<sup>38</sup> Thus, an analysis of existing systems should be used only to assess the availability of state and local programs as resources and not for determining the components of a coordinated system.

Third, the gaps in the statutory infrastructure for food safety are so ubiquitous that only a complete overhaul will serve to create an effective infrastructure. For example, situations like the SBP case, in Texas, would not occur if USDA's Food Safety and Inspection Service (FSIS) had sufficient statutory authority to accomplish what it needs to do in order to effectively enforce HACCP. As a result of the fact that FSIS' authority is perceived, by industry, to be doubtful, FSIS is perceived as vulnerable to challenge and, therefore, FSIS may not be taken seriously in its work.

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<sup>38</sup> The 1999 Food Safety Survey conducted by the Food Practice Consulting Group and CMF&Z asked “Who's doing the best job of assuring food safety?” Consumers ranked the various groups in the following order, placing government agencies sixth out of seven: producers/ farmers; supermarkets; food processors, restaurants; consumers; government agencies; and meat/poultry packers. [www.FoodIssues.org](http://www.FoodIssues.org).

Fourth, only a food safety system that uses national uniform mandatory standards will create a "seamless federal/state/local food safety system." Clearly, state and local resources are necessary to create an effective food safety system. However, this is a time where the federal government must exercise a leadership role. Food safety should not vary from state to state. Consumers should be assured that whether they eat a hamburger in Iowa or on vacation in Florida, that the hamburger will be just as safe. Further, CAFOs should not be able to base their siting decisions on the environmental laws of each state. Laws affecting CAFOs should be uniform across the states so that the health of neighbors living close to such CAFOs is not adversely affected. It is simply not fair to impose such extreme externalities on innocent people simply based on the reason that a state has decided that attracting business to the state is more important than protecting the health of its residents.

The issue of animal waste provides an excellent illustration of the effect of lack of adequate federal regulations. Due to the fact that few states have sufficient regulations covering animal waste, producers have failed to adequately manage the problem. Producers continue to use outmoded waste technology methods, fail to implement changes in animal feed which could help reduce nutrient problems, and fail to implement other technologies that could make animal waste a valuable product. The majority of producers remain in a state of denial that there is even a problem for which they should be responsible.

Examples abound of problems resulting from the lack of regulation. Without even considering the extreme consequences of 1999's Hurricane Floyd on CAFO lagoons, in 1995, 35 million gallons of animal waste spilled into the state's waterways.

In 1997, approximately 450,000 fish were killed in North Carolina by the toxic microbe *Pfiesteria piscicida*, whose increased presence in estuarine waters is linked to excess nutrients from animal waste and farm runoff. Symptoms reported among people with close exposure to *Pfiesteria* in its toxic form include memory loss, respiratory problems and skin rashes. In 1997, a Maryland Environment Department survey of the St. Martin's River, the largest tributary to the state's coastal bays, found "many large piles" of chicken litter, "ranging into the hundreds of tons" near ditches and creeks that feed the main stem.<sup>39</sup> The list of spills, illegal dumping, overapplication of waste to fields, and other waste incidents is endless. Even given the known incidents, which are indeed numerous, the true extent is unknown since many incidents are not reported and go undiscovered.

One of the biggest problems is that even where there is some investigation of a waste incident, and charges filed, the fines and penalties imposed by the states are either non-existent or inadequate.

Even when companies exceed pollution limits and receive notices of violation, regulators rarely follow through with fines. [¶] Early one Saturday last August, a waste water storage lagoon filled at Allen's slaughterhouse in Harbeson, Del. Solids slipped into Beaverdam Creek along with the regular discharge-185,000 gallons of excessively polluted water over four hours. [¶] No one performed tests the state requires to determine the spill's effects, Allen explained, because no one was on duty. The company promised to begin monitoring round-the clock. Delaware authorities levied no fine. [¶] EPA officials and environmentalists say such lenience encourages companies to gamble with the law. "What's the incentive to play by the rules if there's no penalty?" said Jacqueline D. Savitz, executive director of Coast Alliance, an environmental advocacy group.<sup>40</sup>

Thus, it is clear that only a strong federal mandatory regulatory program will be sufficient to fully address this issue.

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<sup>39</sup> An Unsavory Byproduct, Poultry's Price: the Cost to the Bay, The Washington Post, August 1, 1999, at A20.

Finally, we have some questions regarding the “gap analysis and identification of criteria to improve effectiveness of programs at all levels.”

1. Who will perform the “gap analysis and identification?”
2. Will there be an opportunity for consumer stakeholder comment?
3. How long will this process take?

Consumers do not want to create a system that supports a lengthy process before any substantive changes are made. This is the basis of the current system, which, as previously discussed, is simply not working.

**Objective 2: Promote development and implementation of preventive techniques and controls using risk based approaches and establishment of national standards, including performance standards, where appropriate.**

**Action items:**

**Facilitate industry adoption of preventive controls, as appropriate based on risk, throughout the farm-to-table continuum.**

**Maintain performance standard based, HACCP programs and expand the use of this concept where appropriate.**

In light of the recent SBP case, in Texas, how realistic is the use of performance standards? The use of such standards will be effective only if the voluntary aspect of the HACCP system is supported by the enforcement powers of an agency with unequivocal legal authority. It is clear that statutory change is absolutely needed in this area or meat processors will do whatever they want. This is evidenced by the following factual example. After the second failure by SBP to comply with the Salmonella performance standards, FSIS gave SBP an extension of time to install equipment that could reduce cross-contamination. However, the extension was withdrawn when SBP said it was no longer committed to installing the equipment.<sup>41</sup> Now, with the judge’s decision, in the

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<sup>40</sup> Permitting a Pattern of Pollution, Poultry’s Price: The Cost to the Bay, The Washington Post, August 2, 1999, at A11.

<sup>41</sup> Court orders USDA to keep Supreme open until authority issue resolved, Food Chemical News, 3, 24.

SBP case, SBP can continue to market contaminated meat<sup>42</sup> without incurring any consequences. This example illustrates the need for a new statutory structure that provides sufficient legal authority to the single food safety agency to enforce regulations and statutes and recall product without resort to judicial approval.

**Objective 3: Expand and enhance effective monitoring, surveys, inspections and surveillance of foodborne illness and other health effects resulting from food safety hazards.**

**Action items:**

**Monitor hazards and prevention practices.**

**Include microbial, chemical and physical hazards as well as current prevention practices. Programs could include federal and state public health, food safety and animal health data collection; surveys of "high risk" raw agricultural products (e.g. sprouts) and foods at processing; and targeted surveys of agricultural and manufacturing practices. Such monitoring, surveys and surveillance could provide baseline data for risk assessment, detect emerging pathogens, etc. for risk management (including standards and enforcement) and evaluate the effectiveness of hazard reduction programs (quality assurance programs).**

FACT applauds the Plan's inclusion of targeted surveys of agricultural and manufacturing practices. Such surveys may be useful in determining practices which may be contributing to foodborne pathogens in production animals as well as locating animal husbandry practices which may be useful in eliminating pathogens on-farm.

On the other hand, how can animal health data be collected when animal pharmaceutical companies object to providing sales and use data regarding the use of antibiotics used in food animal production?<sup>43</sup> The animal pharmaceutical sales and use data is allegedly considered to be the proprietary property of animal health companies under current statutes. Such information is vital to making informed decisions on the issue of antibiotic resistance. The reason that the animal health industry may not want to

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<sup>42</sup> Supreme Beef Processors (SBP) recalls ground beef due to E. coli 0157:H7 contamination less than a month after a fed. judge ordered USA to keep the plant open, Food Chemical News, January 10, 2000, at 3.



release such information is that it may show a correlation between antibiotic use and antibiotic resistance patterns which could have a grave impact on sales of antibiotics used for the purpose of growth promotion and disease prevention. This view is supported by members of the medical profession who must deal with the consequences of antibiotic resistant bacteria in humans. Mark Zervos, MD, recently stated, that the lack of data regarding the amount of consumption of antimicrobials on farm is a real obstacle to understanding the issue of antibiotic resistance.<sup>44</sup> Thus, this is yet another example of why the current food safety system is not working due to the lack of an adequate and effective statutory structure.

**Develop a network of animal diagnostic laboratories to enhance national, systematic monitoring in animal feeds and feed-stuffs for microbial, chemical and other hazards that pose a food safety risk.**

FACT applauds the inclusion of this action item as it has been shown that animal feeds and feed stuffs can harbor microbial hazards. For example, we know that bovine spongiform encephalopathy is transmitted through the provision of certain types of feed to ruminants. Also, studies have shown that Salmonella is in animal feed. Recently, studies have been finding antibiotic resistant bacteria in poultry litter which is used as animal feed.<sup>45</sup> Thus, monitoring for microbial hazards in animal feeds is essential to an understanding the transmission of foodborne pathogens on farm.

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<sup>43</sup> Sundlof says CVM lacks legal authority for blanket antibiotic ban, Food Chemical News, March 22, 1999, at 4.

<sup>44</sup> Mark Zervos, MD, Epidemiology of antimicrobial resistance in human and animal isolates of Enterococci, Food Safety Symposium on Antimicrobial Resistance, Centers for Disease Control and Prevention, September 24, 1999.

<sup>45</sup> Mark Zervos, MD, Epidemiology of antimicrobial resistance in human and animal isolates of Enterococci, Food Safety Symposium on Antimicrobial Resistance, September 24, 1999, Centers for Disease Control and Prevention; Judy Johnson, PhD, Synercid resistant Enterococcus faecium in a commercial poultry farm, Food Safety Symposium on Antimicrobial Resistance, September 24, 1999, Centers for Disease Control and Prevention; Kirk Smith, DVM, PhD, Current trends in quinolone resistant

**Objective 4: Identify food safety risks and violations of food safety standards through inspections.**

One action item that should be included under this objective is monitoring water quality on-farm. This is important in order to determine whether there are problems with water, on-farm, due to improper disposal of animal waste. Such monitoring should be conducted during on-farm inspections that will be necessary in order to monitor farms for other food safety matters, such as making sure that farms are properly testing for SE.<sup>46</sup> At the meeting of the Council, the FDA affirmed its authority to make on-farm inspections. The problem is that the FDA currently does not have the funds to support such inspections. EPA has a similar problem. Thus, this problem is yet another example of the need for a single food safety agency with a single budget. If the agency had a single budget, it is more likely that the director of the agency would make sure that all food safety programs were adequately funded based on the priority list rather than ensuring funding for entrenched programs that are no longer relevant.

**Action items:**

**Prioritize for inspection those categories of foods determined by risk assessment to pose a "high risk" to public health.**

**For example: meat and poultry, eggs and egg products, seafood, ready to eat food.**

It is unclear what the above-referenced action item means. Does it mean that inspections will continue as they are currently performed until risk assessments are

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Campylobacter jejuni infections in Minnesota, Food Safety Symposium on Antimicrobial Resistance, September 24, 1999, Centers for Disease Control and Prevention; Enzo Campagnolo, DVM, MPH, Investigation into the chemical and microbial constituents of surface and ground water proximal to large scale swine and poultry feeding operations, Food Safety Symposium on Antimicrobial Resistance, September 24, 1999, Centers for Disease Control and Prevention; Charles Hofacre, DV, MAM, PhD, Update on research in food safety from the Department of Avian Medicine at University of Georgia, Food Safety Symposium on Antibiotic Resistance, September 24, 1999, Centers for Disease Control and Prevention.

<sup>46</sup> Egg Safety From Production to Consumption: An Action Plan, December 10, 1999.

completed for all categories of foods? If the answer is yes, then this action item must be changed for the following reasons. First, risk assessments generally take at least two years. For example, the *Salmonella enteritidis* Risk Assessment commenced in December 1996 and was not completed until July 1998.

Another example of a risk assessment that has taken more than a year and a half, and is still incomplete, is a study, by the USDA's office of Risk Assessment and Cost Benefit Analysis (ORACBA) on the issue of how much it will cost to gain the difference between a eight percent reduction in illnesses when eggs are maintained at an ambient temperature of 45 degrees Fahrenheit and a twelve percent reduction in illnesses from cooling eggs immediately after laying to an internal temperature of 45 degree Fahrenheit. The referral to ORACBA occurred in June, 1998. To date, no report has been issued. Furthermore, the ORACBA study is an illustration of an excessive use of risk assessment. Essentially, the ORACBA study seeks to place a value on human lives in determining whether the benefit of a four percent increase in food safety is worth the incremental cost, if any, to egg producers.

Recently, FDA-CVM Director Stephen Sundlof stated that the agency has begun a risk assessment on the issue of virginiamycin resistance and said that the process will take at least two years. Meanwhile, CVM has approved the antibiotic Synercid, a streptogramin, for human consumption. Although streptogramin resistance is currently rare, reservoirs may have been preselected through use of the related drug virginiamycin as a growth promoter in food animals, and the resistance may become more prevalent under the selective pressure of increasing quinupristin/dalfopristin use.<sup>47</sup> Thus, if each

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<sup>47</sup> Quinupristin/dalfopristin, a new addition to the antimicrobial arsenal, *The Lancet* (Commentary), December 11, 1999, Vol. 354, No. 9195.

risk assessment takes approximately two years, people may die before such risk assessments are completed. Such deaths will be needless, in many cases, because certain preventive measures could have been taken prior to the completion of such risk assessments.

The issue of waiting to initiate any actions before risk assessments are completed is disconcerting for another reason. Since many must be done, does the Council intend to have the Plan require that all risk assessments are completed consecutively or concurrently? If it is consecutively, then considering, in the area of animal pharmaceuticals alone, the number of antimicrobial-pathogen combinations for which risk assessments must be performed, the time for completion of all the risk assessments necessary prior to the initiation of some form of rulemaking would extend probably indefinitely.

Second, does the action item contemplate that a risk assessment will be necessary in order to determine and/or change the priority list? Dr. Wes Long has stated that science is but one of six inputs into the risk management decision-making process.<sup>48</sup> The other five factors that should be considered are: public values, economic factors, political realities, technology, and the statutes.<sup>49</sup> There are many illustrations of situations existing in the current food safety system where, based on an analysis of the other factors, a risk assessment is unnecessary in order to recognize the need for a change in priorities with regard to inspections. For example, it is axiomatic that pasteurized egg product is safer than in shell eggs. Yet, there are 120 inspectors for egg products at USDA, and only one

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<sup>48</sup> "What is Risk Assessment, Risk Management and Risk Communication," Presentation by Wesley Long, Ph.D. FDA Associate Scientific Director, JIFSAN, FDA, Center for Veterinary Medicine, Workshop on Risk Assessment and the Establishment of Thresholds. December 9, 1999.

<sup>49</sup> Id.

inspector at FDA, for in shell eggs. This inequity must be addressed immediately. There is absolutely no need for the expense and delay that a risk assessment, to evaluate this priority issue, would incur.

**Design approaches that can be tailored to the needs of different agencies at different levels of government, to guide agencies in targeting prevention and enforcement activities.**

From FACT's perspective, this action item is completely unnecessary because it is only included as a result of the Council's desire to have a better coordinated system rather than establishing a single food safety agency. The mere inclusion of this item illustrates one of the many reasons why the option for a single food safety agency is superior to the other options. By having a single food safety agency, there is no need to develop approaches that "can be tailored to different agencies." All departments within the new single safety agency would use the same approaches and would deal with state and local governments in a uniform manner since programs would be national in form.

**Objective 5: Protect the food supply through consistent training and consistent enforcement of food safety laws and established regulatory requirements.**

**Action items:**

**Allocate enforcement resources on the basis of greatest risks.**

**Target compliance inspections, e.g. inspections targeted at the foods most frequently associated with illnesses and hazards; at facilities with a history of non-compliance and at the most critical points in the farm-to-table chain for occurrence of hazard-producing or hazard-controlling events.**

What purpose do inspections serve, particularly for repeat offenders, if there is nothing that can legally be done for non-compliance, other than to request the company to voluntarily recall the contaminated product? Here again is another example of the need for overhauling the statutory structure for food safety. "Government can order the recall of products like unsafe cars, toys and insecticides-but not food. Health officials must rely

on persuading companies to voluntarily recall tainted meat.”<sup>50</sup> Thus, action items omitted from this section include:

1. Enact recall legislation providing procedures, that provide adequate due process, for the new single food safety agency to recall potentially contaminated product without need for judicial pre-approval.
2. Enact legislation that provides the new single food safety agency with procedures and responses, such as fines and civil penalties, that may be imposed without the need to always seek court pre-approval, but that still provides adequate due process, for failure to comply with performance standards, particularly for repeated violations.
3. Enact legislation requiring on-farm inspections to ensure compliance with SE regulations.

**Objective 6: Encourage the implementation of risk-based, voluntary approaches for improving food safety, where appropriate.**

**Action items:**

**Develop and/or implement programs to address areas where mandatory standards do not exist.**

Use federal interagency task forces, federal/state agreements, and public/private partnerships in this effort.

**Promote voluntary “best practices” and quality assurance programs developed and implemented by industry and/or government.**

For example, encourage implementation of the current Good Agricultural Practices and Good Manufacturing Practices (GMPs) by domestic producers and foreign trading partners.

**Use incentive programs to improve food safety.**

Examples of such programs could include preferential entry Federal programs, info-sharing, or financial incentives.

FACT does not support the use of voluntary programs, in lieu of federal government legislation and regulatory authority, as the solution for protecting the public

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<sup>50</sup> Poisoned Package, The Washington Post, January 16, 2000, 7, 12.

health. The issue of in shell egg production provides an excellent illustration of the reasons that voluntary quality assurance programs do not provide adequate protection against foodborne pathogens.<sup>51</sup>

Currently, a patchwork of state and industry quality assurance programs (QAPs) has arisen in response to the threat of SE.<sup>52</sup> However, the requirements of the various QAPs are far from uniform and participation in the QAPs is not mandatory. Some programs simply recommend biosecurity steps and rodent control programs, while other programs require testing for SE in the laying houses. In the United Egg Producers' "5-Star" Program, testing for verification is required only two to three weeks prior to depopulation. Moreover, there is no uniformity among the QAPs as to what should be done if SE is found on a farm. Further, the United Eggs Producers (UEP) claim that "100 producers have pledged to follow the program guideline. This many producers account for over 100 million laying hens."<sup>53</sup> However, this claim does not state that the producers have actually submitted documentation evidencing complete implementation of the Program, nor does it identify what percentage of egg producers this number represents. Further, in a UEP press release, UEP vaguely stated that "the industry points to its voluntary quality assurance programs, which are implemented on both state and national

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<sup>51</sup> Other voluntary QAPs do exist with varying amounts of producer participation. For example, 40 percent of all renderers currently participate in a voluntary HACCP program. Don Franco, National Renderers Association, Presentation to Feed safety Committee at the Annual Meeting of the United States Animal Health Association. In the National Research Council report entitled, *The Use of Drugs in Food Animals: Benefits and Risks* (1998), while the Report stated 32,000 pork producers who provide 63 percent of the market hogs in the United States are enrolled in the Swine QAP, no figures were provided for poultry, dairy cows or beef cattle. See pages 54-61.

<sup>52</sup> United States General Accounting Office, Report to the Honorable Richard J. Durbin, U.S. Senate, *FOOD SAFETY: U.S. Lacks a Consistent Farm-to-Table Approach to Egg Safety*, July, 1999 ("GAO Report") at p.7. See also, Advance Notice of Proposed Rulemaking for *Salmonella Enteritidis* in Eggs, Federal Register, Vol. 63, no. 96, pp. 27502-27511, released May 19, 1998. See also, The Pennsylvania Egg Quality Assurance Program, the California Egg Quality Assurance Plan, The New England Risk Reduction Program, the New York State Egg Quality Assurance Program, the South Carolina Egg Quality Assurance Plan and the United Egg Producers "Five Star" Program.

levels and participated in by a large percent of egg producers, and the industry funded 'Five-Star' program." However, the press release failed to disclose the exact number of producers participating in QAPs in general as well as in UEP's own 'Five-Star' Program.

Reliance on voluntary programs simply will not provide consumers with confidence that food is safe. Based on the experiences discussed above, there are several problems with such programs. First, there is no publicly available data, aside from data released by the Pennsylvania Egg Quality Assurance Program (PEQAP), as to the number of producer participants in the various producer QAPs. Second, the various QAPs are not uniform. In fact, in some states, some producers may participate in the state QAP while other producers may participate in the UEP 'Five Star' QAP. Thus, consumer confusion may arise since some producers may claim to be participants in the state program and others in the industry program. Further confusion may arise as a result of a lack of consumer awareness as to the components of each QAP and which QAP would provide the best safety protection. Moreover, this confusion may be confounded if the eggs come from another state with a different QAP that may have different requirements than the in-state QAP or the UEP QAP. Finally, a federal mandatory regulatory program would provide protection against other interstate related issues such as producers in one state, without a QAP that includes environmental testing, selling eggs at a lower price than eggs produced in a neighboring state that includes a mandatory environmental testing requirement in its QAP. All producers should be required to play according to the same rules in order to establish a level playing field.

In addition, FACT does not support the reliance on states, in lieu of federal authority, to determine policy issues and/or implement, independent of federal

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<sup>53</sup> Food Safety Digest, March/April 1998 at p. 1



involvement, food safety programs. FACT recognizes that states do play an important role in helping to keep food safe. However, standards should be uniform across the States. To allow the states to make policy determinations, on issues of national importance, creates the potential for wide variation from state to state. The issue of animal waste and the environmental consequences from CAFOs provide guidance here.

For many years, EPA has delegated the majority of its responsibilities regarding non point source pollution to the states. Lack of nationwide uniformity, in environmental laws and regulations governing CAFOs and their animal waste, has encouraged forum shopping by CAFO owners who seek to site their operations in states that are the most hospitable to their operations and which necessarily provide the least environmental protection to neighbors and employees of CAFOs. In December, 1997, a Senate Report concluded,

Animal waste pollution is a national problem, and current Federal regulations are an inadequate solution. There are no regulations at the national level that set specific requirements for the storage or application of manure, nutrient management, animal waste management plans or construction standards. Although many states are grappling with this issue on their own, new minimum environmental standards for animal waste management should be established at the Federal level to ensure nationwide protection of the environment and human health.<sup>54</sup> [emphasis added]

Ignoring this recommendation, the EPA, in the Manual, continues to cede great authority over policy and implementation of the issue of animal waste to the states. To date this policy has not been effective and there is no reason to believe that a continuation

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<sup>54</sup> Animal Waste Pollution in America: An Emerging National Problem, Environmental Risks of Livestock & Poultry Production, Report Compiled by the Minority Staff of the United States Senate Committee on Agriculture, Nutrition, & Forestry for Senator Tom Harkin, December 1997 (Senate Report) at 25.

of this policy, albeit in a different form, will provide any better protection to CAFO neighbors.<sup>55</sup>

**Objective 7: Promote the development and transfer of new technologies and approaches to risk management directed at improving food safety.**

**Action items:**

**Expedite licensing and encourage the development and use of new technologies and safer pesticides.**

While new technologies are important, new technologies are not always necessary to manage a food safety problem. Instead, in many cases, better animal husbandry practices can help diminish or eliminate the problem such that technologies are not essential. For example, one of the key problems stemming from CAFOs are the excess nutrients, including nitrogen and phosphorous, that are included in animal waste. The problems arise when the waste is spread on fields that are oversaturated with nutrients and the nutrients either runoff into waterways or seep through the ground into the groundwater table. One solution to the phosphorous issue, at least with regard to cows, is to simply decrease the amount of phosphorous given to the cows. Scientists at the University of Wisconsin estimate that dairy producers, in the United States, are feeding about 25 percent more phosphorous than recommended by the National Research Council, who compiles nutrient requirements for dairy cattle and other animal species. Many herds receive feed rations averaging 0.48% phosphorous or higher; however, research

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<sup>55</sup> The following example illustrates this point. While Delaware and Maryland have indicated that they intend to limit nitrogen as permits are renewed, Virginia has stated that it has no such plans. "We're trying to do things voluntarily." Said Dennis H. Treacy, Virginia's Director of Environmental Quality. "And it's working." Permitting a Pattern of Pollution, Poultry's Prices: The Cost to the Bay, The Washington Post, August 2, 1999, at A11. However, upon closer scrutiny, it is apparent that such voluntary systems are not working.

But when Virginia biologists visited Parker Creek-which receives discharge from Perdue's slaughterhouse in Accomac-in 1993, they reported: 'Algae abound and the water stinks. Something here is not as it should be.' The plant, the largest on the peninsula, sends more than 2.3 million gallons of water a day into the creek and 'determines the water quality,' a 1995 state memo noted.'

Id.

shows that levels of 0.37-0.40% are adequate for high producing cows without negative effect on milk production, animal health, or reproduction. The scientists recommended that reducing the phosphorous ration will reduce phosphorous output to the environment which will consequently reduce the amount of land required to spread manure.<sup>56</sup> Moreover, an added benefit to the producer of reducing phosphorus is a savings of approximately \$15-18 per cow per year!<sup>57</sup>

Another example of a change in animal husbandry methods that would improve food safety, without the need for new technologies, is in the area of antibiotics that are fed to food production animals on a subtherapeutic basis. The National Research Council, in its report, *The Use of Drugs in Food Animals: Benefits and Risks*, included a variety of animal management practices that have implications for reducing the need for subtherapeutic administration of antibiotics.<sup>58</sup> Such practices focus on manipulating the animal's environment to reduce stress, introduce hygienic measures to reduce exposure to disease and develop methods to enhance immunity.<sup>59</sup> For example, studies have shown that animals that are overcrowded must compete for feed, water and sleeping space and are more susceptible to disease.<sup>60</sup>

In addition, animals harboring subclinical infections might become chronic shedders of pathogens, which can be transmitted to other animals or to humans through direct contact or through food. Often constant vigilance by animal caretakers is essential to prevent timid animals from being crowded away from feed and water or from being subjected to fighting. To avoid such problems, animals must be given appropriate space and should be commingled as little as

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<sup>56</sup> Cutting Phosphorus in Dairy Cattle Feed Will Save Money, Help Environment ARS News Service, January 17, 2000

<sup>57</sup> Watch that ration phosphorous January 2000 W.H. Miner Farm Report

<sup>58</sup> National Research Council, Institute of Medicine, *The Use of Drugs in Food Animals: Benefits and Risks* (1998).

<sup>59</sup> Id. at 162.

<sup>60</sup> Id. at 164.

reasonably possible, and sick or weak animals should be housed separately from their healthy pen-mates.<sup>61</sup>

Other management practices, to avoid the use of growth promoters, recommended by the National Research Council include use of vaccines, competitive exclusion, probiotics, methods to control ambient temperature and heat stress, improved biosecurity measures, and fly and insect control.<sup>62</sup> Finally, the issue of animal waste is once again implicated as a factor in food safety.

If there is one single physical environmental factor that predisposes the animal to a constant source of infection and reinfection, it is moisture. Moisture facilitates the development of a proliferative medium to support most microorganisms. Under hot and humid conditions, such factors as rain, mud, manure, and bedding become even more important, because they can increase the number of mastitis and disease causing organisms present on animals. In this type of environment, disease must be prevented by decreasing exposure to pathogens and increasing animals' resistance to infection. If disease caused by environmental pathogens is a problem, it is imperative that bedding materials be kept as clean and dry as possible. Finely chopped organic bedding materials, such as sawdust, shavings, recycled manure, pelleted corn cobs, peanut hulls, and chopped straw, frequently contain coliforms and streptococci in excess of  $1 \times 10^6$  cfu per gram and might exceed  $1 \times 10^8$  cfu per gram, a number that often increases mastitis and airborne respiratory disease incidence. Inorganic materials such as sand or crushed limestone are preferable to finely chopped organic materials and are recommended to reduce the bacterial load."<sup>63</sup>

FACT recognizes that new technologies may also have a place in helping improve food safety. However, for small farms, the expense of such technologies may be preclusive. Thus, FACT encourages the Council to consider, not only discovery and development of new technologies, but also methods that would allow such technologies to be available to small as well as large farms. For example, in Denmark, there may be one biogas treatment facility for all swine producers within 10 kilometers of the treatment

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<sup>61</sup> Id.

<sup>62</sup> Id. at 162-170.

site. The Danish government subsidizes 70 percent of the system. In the United States., perhaps such a facility could be initially constructed by the government, but could be made available to farms in the area for a fee. This would allow smaller farms to avail themselves of such technology without incurring the capital investment costs. Also, the cost could be offset if a value added product can be produced by the technology.<sup>64</sup>

**Objective 10: Evaluate management of food safety risks.**

**Action items:**

**Evaluate the food safety system periodically.**

**Assessment studies could (1) Identify areas for improvement in existing and newly developed programs, including possible mid-course correction; and (2) Identify areas where new program activity is needed.**

FACT agrees that the food safety system should be evaluated periodically to ensure that it is properly functioning to protect the public health. However, FACT has the following questions regarding the recommended assessment studies.

1. Would these assessment studies be responsive to consumer input as well as input from government and industry?
2. If so, how would such opportunities be made available?

**Risk Communication Goal: The United States food safety system openly and effectively provides information on food safety risks, and education on how to control those risks.**

**Objective 1: Sustain public confidence through effective, open, transparent, and timely information exchange regarding food safety risk, prevention strategies and decision making.**

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<sup>63</sup> Id. at 170.

<sup>64</sup> Recently, at an education session at the U.S. Poultry & Egg Association, several representatives from poultry companies discussed how their respective operations are adding value to products traditionally considered waste. Through a joint venture with AgriRecycle, Perdue Farms is creating a finished pelleted fertilizer that is marketed to fertilizer buyers in the US. All producers are eligible to contract with Perdue AgriRecycle for its no-cost clean-out services. An egg producer, Dixie Egg Co., is working with ETR Enterprises to create a synthetic solid product for sod farms by adding cellulose pulp material to the manure. Such technologies should be made available to even small farms at no, or at a reasonable cost, since the companies will make a profit from the value added product. Speakers discuss poultry industry waste management approaches, Feedstuffs, January 31, 2000 at 3.

Transparency of the process is probably one of the most critical elements necessary to create a food safety system that is perceived by the American public to be actually protective of the public health. However, to date, the transparency policy has not been uniformly followed. For example, the Council, in December, 1999, held non-public meetings with a variety of groups; however, not all groups were invited to attend. The decision-making process as to which individuals or groups were invited to attend such meetings is still unclear.

The process is not truly transparent and often leaves stakeholders, who may have relevant opinions, out of the decision-making. This type of conduct does not instill confidence in consumers. Since the primary proponents of the single food safety agency have been consumer groups, such conduct tends to indicate that the public stakeholder meetings are merely a formality required by certain regulations and that, in fact, the Council's true goal is to simply create a framework for a better coordinated food safety system, rather than actually considering the arguments for each Option listed in the Plan. A great deal of time and effort on the part of government, industry, academia and consumer groups has been spent on developing a new food safety system. Reverting to the old habits of the former food safety system will not create an effective, functioning new food safety system for the second millennium.

**Conclusion:**

FACT wants a single food safety agency headed by a cabinet level official, with legal authority and budgetary control, because that it is the only organizational structure that can adequately address the food safety issues presented in the new millennium.

Simple modifications to the current system and better coordination among the agencies with food safety responsibilities will do nothing to create a cohesive and comprehensive food safety system. New updated statutes and regulations that adequately address contemporary food safety issues, and that will be flexible enough to adapt to the ever increasing and changing issues that arise in this area, must be adopted and implemented.

The new single food safety agency should be empowered with regulatory authority as well as enforcement powers. Action items that must be included are enacting legislation providing constitutionally sufficient recall procedures, that do not require judicial pre-approval, legislation allowing for fines and civil penalties for failure to comply with performance standards, and legislation requiring on-farm inspections to ensure compliance with enacted regulations.

The new food safety system must not make a pretense of placing an emphasis on farm based controls and mitigation strategies that can be used to improve food safety--but, rather, action items must be included in the Plan that show a true commitment to this intent. While new technologies are important, new technologies are not always necessary to manage a food safety problem. Instead, in many cases, better animal husbandry practices can help diminish or eliminate problems such that technologies are not always essential. Such husbandry practices focus on manipulating the animal's environment to reduce stress, introducing hygienic measures to reduce exposure to diseases, altering animal feed and feed practices, and developing methods to enhance immunity.

Further, the Plan must encompass all areas impacting food safety. Thus, the Plan must include action items related to the issue of animal waste. Pathogens, including antibiotic resistant bacteria, have been found in samples from CAFO manure lagoons and

groundwater. Since such bacteria can be passed along the food chain either through water, feed or as foodborne pathogens, animal waste is clearly a food safety issue. Therefore, issues related to animal waste, such as groundwater, odor, abandoned lagoons, poultry litter, and animal waste used as animal feed, must be addressed in the Plan.

The food safety system must emphasize mandatory federal programs based on legislation and statutes rather than relying on voluntary industry plans and/or state food safety programs. While states do play an important role in helping to keep food safe, policy determinations, affecting the national issue of food safety, must be made at a federal level. To do otherwise, will allow a continuation of site location forum shopping by CAFO owners as well as confusion among consumers as to the safety of their food. Further, environmental consequences from CAFOs will continue unimpeded absent an effective federal animal waste regulatory program.

The Plan must continue to place an emphasis on transparency in the process of food safety regulation. Consumer groups, as well as other stakeholders, must be included at every point in the continuum including decisions impacting food safety research, assessment studies for identifying areas for improvement in existing and newly developed programs, the development of new regulations and statutes, and prioritization of food categories for inspection.

Finally, the Plan must ensure that data necessary to performing adequate surveillance of food safety related problems is made available to the new single food safety agency. For example, sales and use data is vital to making informed decisions on the issue of antibiotic resistance and, therefore, any impediments to the acquisition of such data must be removed.



In conclusion, FACT wants a new food safety system that is led by one agency, with one purpose, having clear roles and responsibilities, that can enforce what it regulates, and that starts where food starts-on the farm. Thank you.

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